REMARKS

Claim 33 had been newly added. Claims 17-33 are pending in this application, with claim 17 being the only independent claim. Claims 17-32 have been rejected under 35 U.S.C. §103(a) as unpatentable over U.S. Publication No. 2002/0077627 ("Johnson").

Rejection of claims 17-32 under 35 U.S.C. §103(a)

The Office Action states that Johnson teaches all of Applicants' recited elements. Applicants disagree.

Applicants' recited invention is directed to method of optimizing the distribution of heat or increasing the localization of the heating in tissue using sound energy from outside a body. The problem with using focused sound energy originating outside a body to treat a tumor inside the body is that the tissue in front of the tumor is also heated as this tissue absorbs the sound energy (see paragraph [0005] of the published specification). This problem increases with the depth of the tumor in the body.

According to Applicants' invention, this problem is solved by generating a sound signal in the target region by radiating the sound signal from a sound emitter in response to a pressure-time signal such that a pressure-time course of the sound signals in the target region is not sinusoidal and such that a magnitude of the pressure amplitude of the sound signal in the target region is larger than the expansion amplitude of the sound signal in the target region, wherein the pressure-time signal is not a single sinusoidal pressure-time signal, and adapting the pressure-time signal such that the pressure-time course of the sound signals in the target region is adapted to a specific utilization of the non-linear propagation and attenuation properties of the material in the target region such that an increase in the temperature in the target region produced by the

adapted pressure-time signal is greater than a temperature increase produced by a sinusoidal pressure-time signal having the same power (see paragraph [0016] of the published specification).

Independent claim 17 recites the steps of "generating a sound signal in the target region by radiating the sound signal from a sound emitter in response to a pressure-time signal such that a pressure-time course of the sound signals in the target region is not sinusoidal and such that a magnitude of the pressure amplitude of the sound signal in the target region is larger than the expansion amplitude of the sound signal in the target region, wherein the pressure-time signal is not a single sinusoidal pressure-time signal" and "adapting the pressure-time signal such that the pressure-time course of the sound signals in the target region is adapted to a specific utilization of the non-linear propagation and attenuation properties of the material in the target region such that an increase in the temperature in the target region produced by the adapted pressure-time signal is greater than a temperature increase produced by a sinusoidal pressure-time signal having the same power".

As described in more detail below Johnson fails to disclose the steps of generating and adapting as recited in independent claim 1.

Johnson discloses a method for detecting and treating a tumor using tissue localized volumetric impedance measurement. The method of Johnson includes providing an impedance measurement apparatus having a plurality of resilient members deployable with curvature and configured to sample tissue impedance through a plurality of conductive pathways. The apparatus of Johnson is configured to be coupled to at least one of an energy delivery device, a power supply, a switching device or logic resources. The apparatus of Johnson is then positioned at a selected tissue site and the impedance array deployed to define a sample volume. The

impedance array of Johnson is then utilized to make impedance measurements through a plurality of conductive pathways. Information from the impedance measurements is then utilized to determine a tissue condition of the sample volume. Energy is then delivered from the energy delivery device of Johnson to ablate or necrose at least a portion of the tumor (see abstract of Johnson). As shown in Fig. 2 of Johnson, the impedance measurements and delivery of energy are performed by equipment arranged in the tissue being treated.

The Examiner cites paragraphs [0125] and [0126] of Johnson as teaching Applicants' recited steps of generating and adapting. Applicants submit that Johnson has been misinterpreted.

The cited paragraph [0125] of Johnson relates to measuring impedance by superimposing a measurement signal 20e onto a treatment signal 20t, i.e., the treatment current for tissue ablation (see paragraph [0059]). The power amplitude of the measurement signal is controlled to maintain a selected total signal amplitude 20at (see Fig. 31). By controlling the average power delivered over the duty cycle, higher measurement currents can be used in short pulse duration without appreciably affecting delivered treatment power, system performance or causing additional or unwanted energy delivery to the target tissue site. Thus, paragraph [0125] merely describes that the average power delivered over a duty cycle can be controlled to maximize the measurement currents without affecting the treatment power.

The cited paragraph [0126] of Johnson further describes the superimposed duty cycle measurement on the treatment signal.

The Examiner-cited passages fail to teach anything about a magnitude of the pressure amplitude of the sound signal being larger than the expansion amplitude of the sound signal. If anything, Johnson ensures that the delivered treatment power is not affected by the superimposed signal. Thus, Johnson fails to teach or suggest "generating a sound signal in the target region by

radiating the sound signal from a sound emitter in response to a pressure-time signal such that a pressure-time course of the sound signals in the target region is not sinusoidal and such that a magnitude of the pressure amplitude of the sound signal in the target region is larger than the expansion amplitude of the sound signal in the target region, wherein the pressure-time signal is not a single sinusoidal pressure-time signal; and adapting the pressure-time signal such that the pressure-time course of the sound signals in the target region is adapted to a specific utilization of the non-linear propagation and attenuation properties of the material in the target region such that an increase in the temperature in the target region produced by the adapted pressure-time signal is greater than a temperature increase produced by a sinusoidal pressure-time signal having the same power", as expressly recited in Applicants' claim 17.

Johnson is not concerned with minimizing the heating of tissue in front of a tumor because the ablation device of Johnson is disposed inside the body and proximate to the tumor (see Figs 1 and 2 of Johnson). Thus, heating of tissue in front of the tumor is not a concern. Johnson is only concerned with finding a tumor using impedance measurements of the tumor as compared with impedance measurements of the surrounding tissue.

In view of the foregoing, Johnson fails to teach or suggest the subject matter recited in Applicants' independent claim 17. Accordingly, independent claim 17 is patentable over Johnson under 35 U.S.C. §103(a).

Claims 18-32, which depend from independent claim 17, incorporate all of the limitations of independent claim 17 and are therefore deemed to be patentably distinct over Johnson for at least those reasons discussed above with respect to independent claim 17.

Newly added claim 33

Claim 33 has been newly added. Support for newly added claim 33 can be found in paragraph [0021] of the published version of Applicants' specification.

Claim 33, which depends from independent claim 17, incorporates all of the limitations of independent claim 17 and is therefore deemed to be patentably distinct over Johnson for at least those reasons discussed above with respect to independent claim 17.

Conclusion

In view of the foregoing, reconsideration and withdrawal of all rejections, and allowance of all pending claims is respectfully solicited.

Should the Examiner have any comments, questions, suggestions, or objections, the Examiner is respectfully requested to telephone the undersigned in order to facilitate reaching a resolution of any outstanding issues.

Respectfully submitted,

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